



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0868]

Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning establishment notification of a consignee and consignee notification of a recipient's physician of record regarding a possible increased risk of Trypanosoma cruzi (T. cruzi) infection.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of
Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion--(OMB
Control Number 0910-0681)--Extension

The guidance implements the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to T. cruzi. The use of the donor screening tests are to reduce the risk of transmission of T. cruzi infection by detecting antibodies to T. cruzi in plasma and serum samples from individual human donors, including donors of Whole Blood and Blood Components intended for transfusion. The guidance recommends that establishments that manufacture Whole Blood and Blood Components intended for transfusion should notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood components to establishments or to destroy them within three calendar days after a donor tests repeatedly reactive by a licensed test for T. cruzi antibody. When establishments identify a donor who is repeatedly reactive by a licensed test for T. cruzi antibodies and for whom there is additional information indicating risk of T. cruzi infection, such as testing positive on a licensed supplemental test (when such test is available) or until such test is available, information that the donor or donor's mother resided in an area endemic for Chagas disease (Mexico, Central and South America) or as a result of other medical diagnostic testing of the donor indicating T. cruzi infection, we recommend that the establishment notify consignees of all previously distributed blood and blood components collected during the "lookback" period and, if blood and blood components were transfused, encourage consignees to notify the recipient's physician of record of a possible increased risk of T. cruzi infection.

Respondents to this information collection are establishments that manufacture Whole Blood and Blood Components intended for transfusion. We believe that the information

collection provisions in the guidance for establishments to notify consignees and for consignees to notify the recipient's physician of record do not create a new burden for respondents and are part of usual and customary business practices. Since the end of January 2007, a number of blood centers representing a large proportion of U.S. blood collections have been testing donors using a licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and the consignees to notify the recipient's physician of record.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.